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32182 7590 12/13/2012 David W. Highet, VP & Chief IP Counsel Becton, Dickinson and Company (The Webb Firm) 1 Becton Drive, MC 110 Franklin Lakes, NJ 07414-1880				
			EXAMINER	
			MATTER, KRISTEN CLARETTE	
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1 RECORD OF ORAL HEARING  
2  
3 UNITED STATES PATENT AND TRADEMARK OFFICE  
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6 BEFORE THE PATENT TRIAL AND APPEAL BOARD  
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9 *Ex parte* MICHAEL J. ISKRA  
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12 Appeal 2012-006903  
13 Application 08/928,272  
14 Technology Center 3700  
15 Oral Hearing Held: November 9, 2012  
16  
17

18 Before STEFAN STAICOVICI, JAMES P. CALVE, and  
19 LYNNE H. BROWNE, *Administrative Patent Judges*.  
20

21 APPEARANCES:  
22

23 ON BEHALF OF THE APPELLANT:  
24

25 LARA NORTROP QUEEN, Esquire  
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30

31 The above-entitled matter came on for hearing on Friday, November  
32 9, 2012, commencing at 9:36 a.m., at the United States Patent and  
33 Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Diane  
34 Humke.

P R O C E E D I N G S

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THE USHER: Calendar Number 70, Appeal Number  
2012-6903, Ms. Northrop Queen.

JUDGE STAICOVICI: Thank you.

THE USHER: You're welcome.

JUDGE STAICOVICI: Good morning, Ms. Queen.

MS. NORTHROP QUEEN: Good morning.

JUDGE STAICOVICI: We are ready whenever you are.

MS. NORTHROP QUEEN: Good morning, Your Honors. My name  
is Laura Northrop Queen for the Appellant.

At issue for the Board's consideration this morning is the rejection of  
Independent Claim 1 and Dependent Claims 6 and 9 under 35 U.S.C.  
Section 103(A) in view of the state of the art, as embodied in Figures 1 and 2  
of the specification of the present invention, in view of the Finney reference,  
U.S. Patent 4,358,425, as well as the rejection of Dependent Claims 5, 7 and  
8 also under 35 U.S.C. 103(A) in view of the state of the art, in view of  
Finney; further, in view of the Burns reference, U.S. Patent 5,458,854.

I have brought with me this morning an exemplary product that Claim  
1 reads upon to help illustrate the invention. If I may submit these to the  
Board for consideration?

JUDGE STAICOVICI: Of course.

MS. NORTHROP QUEEN: Just for review, the tube at issue that I've  
provided is with regard to Claim 1, a one-piece collection container  
assembly. It comprises an elongated tubular housing, having a side wall  
extending between a post, first, and second ends, the first end being the open

1 end and the second end being the bottom of the tube; a solid partition in  
2 contact with said side wall positioned within the said housing between the  
3 second ends, forming a closed bottom, if you look down through the opening  
4 in the tube, you will see the closed partition formed sort of midway along the  
5 tube, that's the solid partition element; the housing defining a volume for  
6 specimen collection and containment therein between the first end and the  
7 partition, that's the collection functional volume defined between the open  
8 end and that sort of middle level partition; and the second end forming a  
9 false bottom, comprising a bottom end below the partition, the bottom end  
10 comprising an annular skirt, and a semispherical bottom wherein the  
11 semispherical bottom comprises an opening therein, and that's directed to the  
12 bottom end of the tube that has a rounded aspect to it, as well as the opening.

13         Now, in order to assist in a brief discussion today, I think it would be  
14 helpful to review sort of the history of how this invention, as recited in the  
15 claim, came to be. Standard clinical blood collection containers have a  
16 shape that I'm sure that you're familiar with. They're essentially an  
17 elongated cylinder that includes a fully rounded closed bottom. These  
18 collection containers were typically used for most processing aspects. They  
19 had an internal fill volume of on the order between five and 10 milliliters.  
20 There's an associated array of equipment that has been developed and used  
21 for many, many years that accommodates these particular tubes. This  
22 includes centrifuges, tube collection containers, different kinds of chemical  
23 analyzers. This is all the equipment that has been known in the art for many,  
24 many years.

1           What was found was that for certain segments of the population,  
2 collecting a blood sample of that kind of volume was very taxing, and this is  
3 particularly true with pediatric patients where obtaining a volume of blood  
4 on that order was very, very difficult, so testing procedures were modified so  
5 that many diagnostic tests could be run on a much smaller volume of  
6 specimen. In order to accommodate those tests, certain micro tubes were  
7 developed.

8           If you can imagine on these tubes, if you consider an overall  
9 dimension somewhere between the opening of the tube that I've provided to  
10 you and that partition, they were very tiny and very difficult to manipulate,  
11 so in order to solve this problem a false bottom was placed on the bottom  
12 end of the tube. This allowed a clinician to have something that was much  
13 easier to manipulate and grasp, and it also typically included a much smaller  
14 internal fill volume. It is undisputed that these false bottom collection  
15 containers had a flat planner bottom surface, and that's shown in Figures 1  
16 and 2 of the specification.

17          Now, one of the significant drawbacks with using these kind of  
18 conventional micro collection tubes is that in order to use them in  
19 centrifuges and accompanying equipment, that equipment all had to be  
20 specially modified or specially provided to accommodate the profile of these  
21 new tubes, so it was something different and apart from the standard clinical  
22 equipment that had been used for many years.

23          Now, what the Appellants had realized was that there was a  
24 significant advantage to providing a collection container that has a false  
25 bottom that you can collect a small volume sample in but that's compatible

1 with the standard clinical equipment, and so, as recited in Claim 1, the  
2 second end has a semispherical bottom portion. Now, this allowed these  
3 tubes to be used in all of the conventional equipment that was previously in  
4 place.

5 Now, the examiner has rejected this claim in view of Figures 1 and 2  
6 of the application, known as the state of the art, in view of the Finney  
7 reference. The examiner states on the paragraph bridging pages 3 and 4 of  
8 the final office action that absent a critical teaching and/or showing of  
9 unexpected results from the tube having a semispherical bottom, modifying  
10 the bottom end of the tube shown in Figures 1 and 2 of the subject  
11 application so that it is semispherical is an obvious design consideration that  
12 does not patently distinguish over the prior art.

13 Now, in that same paragraph the examiner goes on to state that  
14 changing the bottom to a semispherical shape would allow the tube to be  
15 compatible with common standard clinical equipment and instrumentation  
16 depending on the exact intended use of the tube, so, in other words, the  
17 inventive future of this claim design is critical because it allows a false  
18 bottom tube to be compatible with standard equipment. This was not  
19 possible with the prior art false bottom tubes that had a flat planner surface.

20 When, like here, the modification of the shape of the claimed object  
21 changes the functionality, it is not a mere design choice, so the fact that  
22 previous flat bottom tubes could be used in centrifuges that were custom  
23 configured to do so does not detract from the criticality of the Appellant's  
24 invention. Rather, the present invention, as recited in Claim 1, is directed to

1 a tube that has a certain shape and provides an important functional  
2 requirement and advantage over what was previously known in the art.

3 So, at this time, the Appellant's position is that the asserted reasons for  
4 modifying the state of the art do not support a finding of obviousness. We  
5 request, respectfully, that you'd reconsider and reverse the examiner's  
6 position.

7 JUDGE STAICOVICI: Doesn't the examiner also use Finney as a  
8 secondary reference?

9 MS. NORTHPROP QUEEN: Yes, it does. Yes, the examiner does.  
10 Finney is directed to a centrifugation tube that has a pierceable septum at the  
11 bottom of the tube so that the bottom rounded portion has a pierceable plug,  
12 if you will, that's accessible by a needle to withdraw a sample from that tube.  
13 That is a standard tube in that it does not have a false bottom and it's  
14 adapted for larger volume collection.

15 The motivation asserted in Finney for rounding the bottom of that  
16 tube is that when the tube is subjected to increased rotational force above a  
17 certain threshold, that rounding the bottom minimizes the potential for  
18 leakage, and that's a significantly different technical feature than providing a  
19 rounded bottom for compatibility with instrumentation.

20 JUDGE STAICOVICI: Any questions --

21 JUDGE CALVE: No.

22 JUDGE STAICOVICI: -- Judge Calve? Judge Browne?

23 JUDGE BROWNE: No.

24 JUDGE STAICOVICI: Thank you.

1 MS. NORTHROP QUEEN: Great. Thank you so much for your time  
2 today. I appreciate it.  
3 (Whereupon, at 9:46 a.m., the proceedings were concluded.)